

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

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TAMARA CARTER and DAVID CARTER,

Plaintiffs,

v.

JOHNSON & JOHNSON; ETHICON, INC.;
and ETHICON LLC,

Defendants.

Case No. 2:20-cv-01232-KJD-VCF

ORDER

Presently before the Court is Defendant's Motion to Limit Testimony of Paul J. Michaels, M.D. (#195). Plaintiffs responded in opposition (#207) and Defendant replied (#216).

I. Factual and Procedural Background

This is a products liability action involving two prescription medical devices— Prolift and TVT. On July 23, 2010, at St. Rose Dominican Hospital in Las Vegas, Nevada, Dr. Gregory Hsieh implanted a Prolift device for Plaintiff Tamara Carter's ("Mrs. Carter") posterior pelvic prolapse and a TVT mid-urethral sling for Mrs. Carter's stress urinary incontinence ("SUI"). Mrs. Carter alleges that these medical devices caused her injuries, and that Defendants are liable under claims of strict liability for failure to warn and for design defect. Her husband, Plaintiff David Carter ("Mr. Carter") raises a loss of consortium claim. Additionally, Plaintiffs claim that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, and grossly negligent. Defendants ("Ethicon") deny Plaintiffs' allegations and assert that Prolift and TVT were state of the art at the time of implant, that Mrs. Carter's alleged injuries pre-dated her surgery, that Mrs. Carter assumed the risks, and that Mrs. Carter's own actions contributed to her injuries.

Dr. Paul J. Michaels is certified in pathology and has been retained by the Plaintiffs to offer his opinions on safer alternative designs. Ethicon objects to this testimony and argue that Dr. Michaels cannot provide reliable, trustworthy, and admissible testimony because his opinions

1 have not been supported by testing.

2 II. Analysis

3 A. Legal Standard

4 Fed. R. Evid. 702 permits a “witness who is qualified as an expert by knowledge, skill,
5 experience, training, or education [to] testify in the form of an opinion or otherwise if: (a) the
6 expert’s scientific, technical, or other specialized knowledge will help the trier of fact to
7 understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient
8 facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the
9 expert has reliably applied the principles and methods to the facts of the case.” The Supreme
10 Court gave expanded direction on Rule 702 in Daubert v. Merrell Dow Pharmaceuticals, Inc.,
11 509 U.S. 579 (1993). In Daubert, the Court held that Rule 702 imposed “a special obligation
12 upon a trial judge to ‘ensure that any and all scientific testimony... is not only relevant, but
13 reliable.’” See Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999). The Court expanded this
14 gatekeeping obligation to all expert testimony. Id. at 147. Daubert “established that, faced with a
15 proffer of expert scientific testimony, the trial judge, in making the initial determination whether
16 to admit the evidence, must determine whether the expert’s testimony reflects (1) “scientific
17 knowledge,” and (2) will assist the trier of fact to understand or determine a material fact at
18 issue.” Daubert, 509 U.S. at 592. The “focus must be solely on principles and methodology, not
19 on the conclusions that they generate.” Id. at 595.

20 The Ninth Circuit has emphasized that “Rule 702 is applied consistent with the liberal thrust
21 of the Federal Rules and their general approach of relaxing the traditional barrier to opinion
22 testimony.” Jinro Am. Inc. v. Secure Investments, Inc., 266 F.3d 993, 1004 (9th Cir. 2001). “An
23 expert witness—unlike other witnesses—is permitted wide latitude to offer opinions, including
24 those that are not based on firsthand knowledge or observation, so long as the expert’s opinion
25 [has] a reliable basis in the knowledge and experience of his discipline.” Id. (citations and
26 quotation marks omitted).

27 In Daubert, the Court also clarified that parties should not be “overly pessimistic about the
28 capabilities of the jury and of the adversary system generally.” Daubert, 509 U.S. at 596.

1 “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the
 2 burden of proof are the traditional and appropriate means of attacking shaky but admissible
 3 evidence.” Id. “The role of the Court is not to determine ‘the correctness of the expert’s
 4 conclusions but the soundness of his methodology.’” Great W. Air, LLC v. Cirrus Design
 5 Corporation, No. 2:16-CV-02656-JAD-EJY, 2019 WL 6529046, *3 (D. Nev. 2019). “The judge
 6 is supposed to screen the jury from unreliable nonsense opinions... [t]he district court is not
 7 tasked with deciding whether the expert is right or wrong, just whether his testimony has
 8 substance such that it would be helpful to a jury.” Id. at 4.

9 **B. Dr. Paul J. Michaels’ Testimony**

10 Dr. Michaels discussed general alternative mesh designs that do not present the same risks as
 11 the polypropylene in TVT and Prolift, including absorbable mesh materials and mesh with larger
 12 pores. Ethicon argues that these opinions are unsupported by testing and scientific literature.
 13 (#195, at 4). Ethicon references the Daubert factors in Cooper v. Brown, 510 F.3d 870, 880 (9th
 14 Cir. 2007), and argues that testing is necessary and without it, his opinion is unreliable. (#195, at
 15 6). The Court in Daubert clarifies that “[m]any factors will bear on the inquiry, and we do not
 16 presume to set out a definitive checklist or test.” Daubert, 509 U.S. 579 at 593. Daubert also says
 17 that “the inquiry envisioned by Rule 702 is, we emphasize, a flexible one” and the “overarching
 18 subject is the scientific validity and thus the evidentiary relevance and reliability— of the
 19 principles that underlie a proposed submission.” Id. at 594–95. The Ninth Circuit also
 20 emphasized that expert witnesses are “permitted wide latitude to offer opinions... so long as the
 21 expert’s opinion [has] a reliable basis in the knowledge and experience of his discipline.” Jinro
 22 Am. Inc., 266 F.3d at 1004. The Court determines that Dr. Michaels’ opinion is admissible
 23 because it is based on valid scientific principles and methods, and because of his expertise in
 24 pathology.

25 In Dr. Michaels’ expert report, he cites to “[a] study of modified mesh material used
 26 experimentally in a surgical setting that contained a mixture of non-absorbable polypropylene
 27 and absorbable polyglactin showed that reducing the amount of polypropylene (non-absorbable)
 28 to less than 30%... significantly reduced the degree of inflammation[.]” (#195-1, at 3). He also

1 refers to a separate study in dogs showing that absorbable material showed less inflammation
2 than monofilament polypropylene grafts. Id. He indicated that more generally, other studies have
3 supported the finding that larger mesh pore sizes have better incorporation into the surrounding
4 native tissues. Id. Dr. Michaels also cited Dr. Klinge, who “found that the degree and quality of
5 the fibrosis was directly related to the amount of the inflammatory reaction and associated
6 foreign body reaction at the interface between the mesh and the patient’s tissue.” Id. at 6.
7 Further, Dr. Michaels cited a presentation by Ethicon’s Research and Development department
8 that an “ideal vaginal mesh... would be lightweight and with a large pore size.” Id. at 7. The
9 Court finds that, consistent with the Ninth Circuit’s emphasis on “relaxing” the barrier to opinion
10 testimony, and with the Supreme Court’s guidance in Daubert, Dr. Michael’s opinion rests on
11 reliable science. Additionally, Ethicon will have the opportunity to cross-examine Dr. Michael
12 and attack his credibility in the presence of the jury. The Court is tasked only with screening the
13 jury from unreliable and nonsense opinions and not with determining the correctness of an
14 expert’s conclusions. See Great W. Air, LLC, 2019 WL 6529046, at *3.

15 In Dr. Michaels’ deposition, he testified that from “his point of view as a pathologist,”
16 smaller pores are much more likely to cause bridging fibrosis. (#195-3, at 11). He goes on to
17 describe his method as a pathologist for identifying evidence that pores in mesh are causing a
18 complication. Id. However, he also testified that he does not have an opinion on how large the
19 pores should be to avoid bridging fibrosis. Id. Also in his deposition, he testifies that he would
20 not tell a surgeon which material to use on a particular patient. Id. at 26. Finally, he testified that
21 he does not have any opinion in particular about whether Ethicon should have used a certain
22 material in the mesh used for treatment of stress urinary incontinence or pelvic organ prolapse.
23 Id. Although his testimony is admissible, for these reasons, the Court limits the testimony to
24 include only his point of view as a pathologist in identifying complications in mesh, as well as
25 the scientific literature and methods he relied on to conclude that generally, absorbable materials
26 with larger pore sizes are less likely to cause inflammation. These topics are also still subject to
27 cross examination. It does not appear that Dr. Michaels intended to opine on what specific
28 material a surgeon should use in contrast to what was used, and insofar as he does attempt to do

1 so in trial, he will be precluded. (#195-3, at 25–26).

2 III. Conclusion

3 Accordingly, **IT IS HEREBY ORDERED** that Plaintiffs’ Motion to Limit Testimony of Paul
4 J. Michaels, M.D. (#195) is **GRANTED** in part and **DENIED** in part.

5 DATED this 28 day of September 2022.

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8 Kent J. Dawson
9 United States District Judge
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